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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624,475

07/23/2003

Warren Hugh Finlay

364-Ius

7427

20212

7590

12/01/2005

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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/624,475	Applicant(s) FINLAY ET AL.	
	Examiner Konata M. George	Art Unit 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Claims 1-13 are pending in this application.

#### ***Drawings***

1. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

#### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on June 21, 2004 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Maitra et al. (US 6,579,519 B2).

Maitra et al. discloses a preparation of nanoparticles comprising a drug, wherein the polymeric micelles nanoparticles are mixed with an alcoholic solution followed by lyophilizing the micelle to get a dry powder for subsequent use (col. 8, lines 38-49).

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4. Claims 1, 3-5 and 7-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Edwards et al. (WO 03/043586 A2).

Edwards et al. discloses a process for formulating particles comprising a "feed solution" of "feed mixture" comprising nanoparticles and one or more additives that are fed to a spray dryer (page, 9, lines 9-12). Lines 13-24 teach that organic and aqueous solvents can be present in the mixture. Bioactive agents having therapeutic, diagnostic and prophylactic properties, nutraceutical agents, radioactive material i.e. by  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $^{35}\text{S}$  and  $^3\text{H}$ , etc. (page 12, line 19 through page 16, lines 8). Page 22, lines 12-13 teach that the particles of the composition are suitable for pulmonary use. Page 23, lines 27-30 teach that the particles size is at least 5 microns.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (WO 03/043586 A2) as applied to claims 1 and 3-5 and 7-13 above.

Edwards et al. discloses a process for formulating particles comprising a "feed solution" of "feed mixture" comprising nanoparticles and one or more additives that are fed to a spray dryer (page, 9, lines 9-12). Lines 13-24 teach that organic and aqueous solvents can be present in the mixture. Bioactive agents having therapeutic, diagnostic

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and prophylactic properties, nutraceutical agents, radioactive material i.e. by  $^{125}\text{I}$ ,  $^{131}\text{I}$ ,  $^{35}\text{S}$  and  $^3\text{H}$ , etc. (page 12, line 19 through page 16, lines 8). Page 22, lines 12-13 teach that the particles of the composition are suitable for pulmonary use. Page 23, lines 27-30 teach that the particles size is at least 5 microns. A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). The prior art does not teach breaking up the dried mixture.

While the prior art does not explicitly teach breaking up a dried mixture, in column 6, lines 52-56 teach a solvent evaporation of the particles while stirring. It is the position of the examiner that stirring the particle mixture while drying would prevent the particles from clumping. Therefore, it is the position of the examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to break up the dried mixture of particles in any manner to facilitate the aerosol delivery of the particles to the lung.

### ***Conclusion***

6. Claims 1-13 are rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is


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(571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER